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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,858	03/02/2005	Hiroyoshi Hidaka	8279.829USWO	5428

7590 05/06/2008

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
05/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,858	HIDAKA ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed **1/10/08** presents remarks and arguments to the office action mailed **7/18/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 15-16 and 27 are pending and examined.

Withdrawn Claim Rejections - 35 USC § 112

Applicant amended claims by specifically stating the types of cancers, thus the broad teaching is now narrowed to only those cancers cited.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-16 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Nature of the Invention: The claims are drawn to the method for treating a patient suffering from leukemia, lung, breast and prostate cancers administering a therapeutically effective amount of compounds of (E)-4- [2- [2- [N- [(p-methoxyphenyl) sulfonyl] amino] phenyl] ethenyl] pyridine l-oxide for example with other antitumor agents such as cisplatin for example, however, the preparations of these compounds in instant claim 27 are not set forth to enable one skilled in the art to make and use .

The incorporation of the references WO 95/2769 for example on page 16 is in Japanese for the making of the preferred compound 3.

Guidance of the Specification: The guidance given by the specification as to how one would make these compounds are lacking because the making of the compounds of the instant claims may not be supported by for the essential subject matter. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass the use of several compound of instant claim 27, but fail to show how these compound are made.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the synthesis of these compounds I would make practicing the claimed invention unpredictable in terms of synthesis.

Claims 15-16 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutically effective amount of 25 mg, 50

mg and 100 mg for compound 2 and 2.5 mg, 5 mg and 10 for cisplatin (CDDP) does not reasonably provide enablement for other ranges of dosages. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Nature of the Invention: the nature of the invention is such that it encompasses a wide range of therapeutically effective amount.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass the use of several compounds with a broader dosage range.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the other dosages that will give synergistic effect in combination of

these compounds of instant claim 27 with carboplatin and cisplatin make practicing the claimed invention unpredictable.

The examiner suggest adding "synergistic inhibitory effect" be added to the amended claims.

Maintained Claim Rejections - 35 USC § 103 (in Part)

Applicant argues that the cited references do not teach any of the claimed compounds when combined with antitumor agents such as cisplatin and carboplatin showed an unexpected result.

In response, this is found persuave in part only for the claimed compounds 2 and 3 (E) -4- [2- [2- [N-acetyl-N- [(p- met-hoxyphenyl) sul fonyl] amino] phenyl] ethenyl] pyridine 1 – oxide.

Via the data submitted it is not indicated how these other compounds will respond to combination. Finding synergism in one compound does not necessitate that every compound cited by the Applicant will respond in the same manner as the shown data. In fact the data of Table I only shows compound 2 with CDDP (cisplatin) it does not include carboplatin, the assertion that the compounds of instant claim 27 when combined with CDDP and carboplatin will give a synergistic effect. It is also noted that the claims are such that any therapeutically effective amount is considered. In the disclosure applicant only showed 3 sets of dosages however, the claims are inclussive of other dosages.

Based on the reasons given above the rejection is maintained.

Claims 15-16 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al., US 5,972,976 in view of Goodman and Gilman, The Pharmacological Basis of therapeutics,and Ragaz et al., The new England J. of Med. (As in the office action of record).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
4/18/08

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614